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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,580	04/24/2001	Andrea Califano	Y0R920000687US2	5406
7590	09/16/2004		EXAMINER	
Ryan, Mason & Lewis, LLP Suite 205 1300 Post Road Fairfield, CT 06430			CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/841,580	CALIFANO ET AL.
	Examiner	Art Unit
	Lori A. Clow, Ph.D.	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3, 17-19 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3, 17-19, and 23-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 August 2004 has been entered.

Claims 1-3, 17-19, and 23-25 are currently pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Non-Statutory Subject Matter

Claims 1-3 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to **non-statutory subject matter**.

Applicant argues that “claim 1 recites deriving a transformation” and that that “transformation is clearly and “immediately useful” outcome of the method, as it can be used to convert gene expression signals into transformed gene expression signals”. Applicant further asserts that “the present techniques teach that a control matrix can be formed”. However, the fact remains that the **claimed** method to transform gene expression signals comprising determining the signals and deriving transformations using a function to create the transformation is only mathematical manipulation of the data generated from expression signals.

A method which transforms gene expression signals to find certain patterns of expression MAY be one which produces a concrete, tangible, and useful result. However, some knowledge is required with regard to a specific pattern that result from such a method, for example. **In the instant claims**, there is no specificity identified as to what is intended by the outcome of the method. Therefore, the invention does not meet the standard of being immediately useful. Furthermore, there is no particular data identified or specific patterns recited in the specification such that a concrete, tangible, useful result is readily apparent. Applicant argues that “the phenotype matrix has columns corresponding to genes and rows corresponding to particular experiments. The experiments may be from cells that exhibit a certain disease phenotype, for example diabetes or cancer”. This is not persuasive because there is still no recitation of what to do with the probabilities generated or how that result of the method is concrete, tangible or useful. The claimed method is not even directed to a phenotype matrix for determining patterns. The method for transforming gene expression signal remains a mere mathematical manipulation of data with no stated outcome and is therefore not immediately concrete, tangible, or useful.

As set forth in MPEP 2106: “For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing O'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible, and useful result; i.e., the method recites a step or act of producing something that is concrete,

Art Unit: 1631

tangible, and useful. See AT&T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible, and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and /or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc).”

Furthermore, not all processes are statutory under 35 USC 101, as put forth in *Schrader*, 22 F.3d at 296, 30 USPQ2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technical arts is either disclosed in the specification or would have been known to the skilled artisan or (B) be limited to a practical application within the technological arts.

Utility

Claims 1-3, 17-19, and 23-25 remain rejected under 35 U.S.C. 101 because the **claimed** invention lacks patentable utility.

Applicant argues that “the specification clearly teaches that transformations are derived, wherein a probability density distribution is transformed into a uniform probability.” However, the **claims** recite a method for transforming gene expression signals. The specification teaches that transformation of data can be used for identification of patterns in healthy verses unhealthy phenotypes such that these patterns may then be used to characterize an unknown sample into one of those two classes (page 6, lines 23-27; page 7, lines 1-2). However, the **claimed** method still is not directed to the steps of **classifying unknown samples into phenotype groups**. It is merely directed to transforming data that represent gene expression signals. The specification does not teach any specific, substantial, or well-established utility for a method that simply

transforms expression signal data by itself. Use of the claimed method to analyze the expression signals such that patterns are identified is certainly of scientific interest; however, no specific, substantial, and credible utility is set forth for the mere transformation of data as the “use” gained from this transformation is not disclosed or claimed. Utilities that require further research to identify or reasonably confirm a real-world context of use are not substantial utilities (See MPEP 2107.01). Therefore the claimed method does not have utility.

Applicant argues that the utility is “that of creating a uniform distribution of transformed gene expression signals”. However, what one does with this transformed data is not stated. What is the result of the transformation process? The claimed method simply converts signals to a uniform distribution, without any further steps for an immediately useful application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 17-19, and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

Claims 1-3, 17-19, and 23-25 recites “deriving a transformation that **creates**, within a selected interval, a uniform distribution”. The specification does not teach a transformation that

creates a uniform distribution. Applicant points to support for this amendment in original claim 3, as well as, at page 14, lines 9-17 and 24-27. However, the Examiner fails to see where a transformation creates a distribution. Original claim 3 read “a transformation that approximates the distribution”. Further, page 14 states that “each transformation takes a probability density distribution and **transforms** this to a uniform probability distribution” and “each transformation corresponds to one of the genes and is used to **convert** the expression levels of entries that correspond to the gene to a transformed value”. However, nowhere does the transformation create a uniform distribution.

Prior Rejections Withdrawn

Claim rejections under 35 USC 112, 2nd paragraph from the previous Office Action are hereby withdrawn in view of Applicant's amendments.

Claim rejections under 35 USC 103 from the previous Office Action are hereby withdrawn in view of Applicant's response.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Art Unit: 1631

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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September 14, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

*September 14, 2004
Lori A. Clow
9/14/04*